



# A Real Burn: Sunscreen Labeling in the Face of FDA Inaction

## Citation

Lisa Boychenko, A Real Burn: Sunscreen Labeling in the Face of FDA Inaction (May 2011).

## Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8965639>

## Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA>

## Share Your Story

The Harvard community has made this article openly available.  
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

# **A Real Burn: Sunscreen Labeling in the Face of FDA Inaction**

By Lisa Boychenko  
Harvard Law School, Class of 2011  
May 2011

## **Abstract**

As rates of skin cancer continue to rise, sunscreen continues to be an essential tool in the fight against harmful UV radiation emanating from the sun. Sunscreen labeling greatly impacts the public's perception of the risks of sun exposure, the protection obtained from a particular product, and the proper use of sunscreen. Thus, FDA regulation of sunscreen to prevent misleading labeling is an important aspect of public health. FDA began the rulemaking process for sunscreen products in 1978, but has yet to issue a final monograph that would legally bind sunscreen manufacturers. This prolonged rulemaking has resulted in many conclusions and proposed rules that would regulate sunscreen labels in order to encourage proper understanding of sun exposure danger and proper use of sunscreen products. However, since the regulations are not binding, manufacturers need not comply with FDA's rules. Thus, the public has not benefited from FDA's thorough analyses and proposed solutions to labeling, but instead has suffered and continues to suffer from FDA inaction.

## Introduction

Sunscreen has long been a staple of American outdoor activity. As we move further into the twenty-first century, it seems certain that the desire for tan skin and sun soaking vacations is here to stay. And it also seems clear that skin cancer is here to stay. The incidence rate of melanoma has been increasing for the past thirty years.<sup>1</sup> As of 2006, its incidence rate has increased over 500% in the previous fifty years, which is the fastest increase of any cancer type.<sup>2</sup> Rates of the more common, but less deadly, basal and squamous cell skin cancers have also been on the rise for many years.<sup>3</sup> In fact, skin cancer is by far the most common type of cancer,<sup>4</sup> and thus presents an immediate challenge to our country. As our understanding of the sun's potential to damage our health grows, our reliance on sunscreen products increases. This is evident in the seemingly endless climb of SPF values of sunscreen products.<sup>5</sup> Demand exists for products that advertise strong sun protection; but as Americans attempt to take control of their health in the drug store aisle, are they being misled by the numerous bottles that attempt to lure them into a purchase?

Each time a person applies sunscreen and steps outside, she is implicitly performing a cost-benefit analysis to decide if her activity is worth the risks of the sun. Yet the knowledge she relies on to make this decision is likely confined to the few recognizable terms on the bottle of sunscreen. A popular Neutrogena sunscreen states that it is “ultra sheer dry-touch sunblock.”<sup>6</sup> This raises a number of questions. How can “dry-touch” be used to describe a liquid sunscreen?

---

<sup>1</sup> American Cancer Society, <http://www.cancer.org/Cancer/SkinCancer-Melanoma/DetailedGuide/melanoma-skin-cancer-key-statistics> (last visited May 3, 2011).

<sup>2</sup> Melody J. Eide & Martin A. Weinstock, *Public Health Challenges in Sun Protection*, 24 DERMATOLOGICAL CLINICS 119, 119 (2006).

<sup>3</sup> American Cancer Society, <http://www.cancer.org/Cancer/SkinCancer-BasalAndSquamousCell/DetailedGuide/skin-cancer-basal-and-squamous-cell-key-statistics> (last visited May 3, 2011).

<sup>4</sup> *Id.*

<sup>5</sup> See Uli Osterwalder & Bernd Herzog, *The Long Way Towards the Ideal Sunscreen—Where We Stand and What Still Needs To Be Done*, 9 PHOTOCHEMICAL & PHOTOBIOLOGICAL SCIENCES 470, 477 (2010).

<sup>6</sup> Neutrogena Ultra Sheer® Dry-Touch Sunblock SPF 80+

What is sunblock? Will this sunscreen actually block the sun's rays from the skin? Is it better than a bottle labeled "sunscreen"? What does "SPF 85+" mean? Is this value as much of an improvement over SPF 30 as it seems? What does "broad spectrum uva-uvb" mean? Does this product fully and equally protect against UVA and UVB radiation? Furthermore, what does "waterproof" actually mean? Does water have any effect on the strength of this sun protection? Are all "waterproof" sunscreens comparable? Why do other sunscreen products contain labels stating "water resistant"? What about sweat? Perhaps consumers believe these terms simply mean what they seem to. After all, the Food and Drug Administration (FDA) must have regulations to protect consumers from being misled about such an essential health product.

In reality, sunscreen exists in a regulatory grey area. FDA recognizes it as an over the counter (OTC) drug, and it has been the subject of mostly unfinalized rulemaking since 1978.<sup>7</sup> Thus, in spite of thorough analyses and conclusions regarding many labeling issues, sunscreen manufacturers are not subject to FDA enforcement on these issues. Of course, sunscreen is still subject to broader legislation regarding safety and misbranding,<sup>8</sup> but most of the detailed sunscreen regulations that have been written are not in effect. While FDA sorts through continuous scientific research, the public is left largely to the advertising whims of sunscreen manufacturers and executives.

This paper will address the regulatory background that has led to this state of uncertainty, the large labeling issues that continue to place consumers at risk, and the potential future effects of FDA inaction. It concludes that the failure to finalize sunscreen regulations has deprived the public of health protection and knowledge. By delaying the implementation of rules in order to

---

<sup>7</sup> FDA Rulemaking History for OTC Sunscreen Drug Products, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm072134.htm> (last visited May 3, 2011).

<sup>8</sup> Sunscreen Drug Products for Over-The-Counter Use; Final Monograph, 64 Fed. Reg. 27666, 27668 (May 21, 1999).

wait for state of the art science, FDA has withheld valuable labeling protections from the public. The future remains uncertain, but Americans would benefit from an imminent resolution.

## Sunscreen Basics

In the advance notice of proposed rulemaking issued in 1978, FDA concluded that over-exposure to the sun damages the skin and can lead to skin lesions and skin cancer.<sup>9</sup> As it is now widely known, sunscreen provides protection from many harmful effects of the sun, such as photoaging and skin cancer.<sup>10</sup> Sunscreen products absorb, reflect, or scatter ultraviolet (UV) waves that deliver harmful radiation to the skin, thereby decreasing the amount of radiation that would otherwise be exposed to the skin.<sup>11</sup> The sun protection factor (SPF) is the standard measurement for UVB radiation effects, as it measures erythema, commonly referred to as sunburn, caused by UV radiation.<sup>12</sup> UVA protection, which can be evaluated by many different efficacy tests, is typically referred to in more qualitative terms, such as “broad spectrum” protection.<sup>13</sup> Thus, sunscreen products affect the way that UV radiation interacts with the body in an effort to decrease the harmful effects of exposure to sunlight.

One legal aspect of sunscreen is clear: it is classified as a drug under the Federal Food, Drug, and Cosmetic Act (FD&C Act).<sup>14</sup> The FD&C Act provides that “drugs” include “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals,” as well as “articles (other than food) intended to affect the structure or any

---

<sup>9</sup> Sunscreen Drug Products for Over-The-Counter Human Use, Notice of Proposed Rulemaking, 43 Fed. Reg. 38206, 38209 (Aug. 25, 1978).

<sup>10</sup> Eide, *supra* note 2, at 119.

<sup>11</sup> J F. Nash, Paul R. Tanner & Paul J. Matts, *Ultraviolet A Radiation: Testing and Labeling for Sunscreen Products*, 24 DERMATOLOGIC CLINICS 63, 63 (2006).

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> Sunscreen Drug Products for Over-The-Counter Use; Final Monograph, 64 Fed. Reg. 27666, 27668 (May 21, 1999).

function of the body of man or other animals.”<sup>15</sup> FDA has concluded that sunscreen may help reduce the risk of skin lesions, cancer, and other diseases, and that active ingredients in sunscreen affect the structure and function of the body by absorbing, reflecting, or scattering rays of the sun and thus changing the physiological response to solar radiation.<sup>16</sup> Furthermore, FDA has concluded that the key to a sunscreen’s classification as a drug is the presence of a sunscreen active ingredient, in conjunction with labeling claims that the product affects the structure or function of the body.<sup>17</sup> Therefore, tanning products that claim to affect the function of the body, as well as other products such as lipsticks and moisturizers that contain sunscreen are all classified as drugs.<sup>18</sup>

In spite of clear statements from FDA affirming that sunscreen is a drug, comments were still submitted in response to the tentative final monograph of 1993 that suggested sunscreen should be regulated as a cosmetic.<sup>19</sup> Nonetheless, FDA appears committed to the current classification, as the designation of cosmetics containing sunscreen with sunscreen terminology was codified in the final monograph of 1999.<sup>20</sup> In addition, FDA added a requirement of a warning statement on suntanning preparations that do not contain a sunscreen ingredient.<sup>21</sup> These items include products that intend to give the appearance of a tan through either UV radiation exposure or color additives.<sup>22</sup> The label must warn consumers that the product does not contain a sunscreen, the product does not protect against burn, and that exposure of unprotected

---

<sup>15</sup> 21 U.S.C. § 321(g)(1)(B); 21 U.S.C. 321(g)(1)(C) (2008).

<sup>16</sup> 64 Fed. Reg. at 27668.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> 21 C.F.R. § 700.35 (1999). While the bulk of the 1999 Final Monograph was stayed, this section, addressing cosmetics containing sunscreen, was placed in effect. *Id.*

<sup>21</sup> 21 C.F.R. § 740.19 (1999).

<sup>22</sup> *Id.*

skin while tanning may increase the risk of skin cancer, even if the skin does not burn.<sup>23</sup> FDA, therefore, has taken a firm stance on the classification of sunscreen as a drug. Through the labeling requirements of cosmetics that do not contain sunscreen, FDA has taken concrete steps to assist consumers in distinguishing between products that are drugs and those that are merely cosmetics that do not provide sun protection. It has not, however, taken similarly strong steps in assisting the public once the drug classification has been made.

### **The OTC Monograph Scheme and Sunscreen's Procedural Complications**

FDA has set up a regulatory procedure to classify OTC drugs as generally recognized as safe and effective and not misbranded. In order to accommodate the vast amount of products, many of which are similar to one another, FDA created a process to approve drugs that are generally recognized as safe by category in 1972.<sup>24</sup> This allowed generally safe drugs to bypass the new drug application (NDA) process, which can be burdensome and expensive. Through the use of advisory panels, data review, and public comments, FDA created a procedure to establish monographs for OTC drugs.<sup>25</sup>

The monographs establish conditions under which a particular drug can be recognized as safe and effective and not misbranded.<sup>26</sup> The conditions may include active ingredients, labeling indications, warnings, adequate directions for use, and other conditions relating to the safety and effectiveness of the drug.<sup>27</sup> They are established through a lengthy process, whereby the advisory panels recommend a monograph to the Commissioner, who then publishes a proposed

---

<sup>23</sup> *Id.*

<sup>24</sup> Sunscreen Drug Products for Over-The-Counter Human Use, Notice of Proposed Rulemaking, 43 Fed. Reg. 38206, 38206-07 (Aug. 25, 1978).

<sup>25</sup> 21 C.F.R. § 331.10 (2010).

<sup>26</sup> 21 C.F.R. § 331.10(a)(5)(i) (2010).

<sup>27</sup> *Id.*



monograph in the Federal Register. After receiving and reviewing comments to the proposed monograph, a tentative final monograph is published in the Federal Register. After an additional round of comments and a potential for an oral hearing, the Commissioner publishes a final monograph in the Federal Register.<sup>28</sup>

The process of regulating sunscreen through the OTC monograph scheme has been quite lengthy. In 1978 FDA issued an advance notice of proposed rulemaking for sunscreen drug products in the Federal Register.<sup>29</sup> Following this notice, a slew of procedural hurdles followed: extension of the comment period, corrections, reopening of the administrative record, public meetings, and so forth.<sup>30</sup> In 1993 FDA published the tentative final monograph for sunscreen, and then in 1999 the final monograph was issued.<sup>31</sup>

In 2001 however, before the date on which the monograph was to become effective, FDA issued a partial stay of the rule. The bulk of the monograph fell into the “partial” description, thereby leaving numerous labeling regulations suggested, but not required.<sup>32</sup> FDA stated that it made the decision to stay the rule in order to address formulation, labeling, and testing requirements for UVA and UVB protection and create a comprehensive sunscreen final monograph.<sup>33</sup> This effort to be comprehensive, however, has pushed back the implementation of important regulations that are unrelated to the UVA and UVB issues.

---

<sup>28</sup> 21 C.F.R. § 331.10 (2010).

<sup>29</sup> 43 Fed. Reg. at 38206.

<sup>30</sup> FDA Rulemaking History for OTC Sunscreen Drug Products, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm072134.htm> (last visited May 3, 2011).

<sup>31</sup> *Id.*

<sup>32</sup> Sunscreen Drug Products for Over-the-Counter Human Use; Partial Stay, 66 Fed. Reg. 67485, 67485 (2001).

<sup>33</sup> 66 Fed. Reg. at 67485.

## The 1999 Final Monograph

The final monograph that was released in 1999 incorporated provisions from the tentative final monograph, in addition to provisions addressing comments to the tentative final monograph, that provided great benefits to consumers. FDA's conclusions to the comments received as well as the actual monograph contain many provisions and statements regarding sunscreen labeling policies. The following discussion presents an examination of some of the labeling decisions set forth in the final monograph.

One major change that was to be implemented in the 1999 final monograph was a new SPF labeling scheme. In spite of numerous comments objecting to the change, FDA concluded that "an SPF 30 sunscreen product provides adequate protection for the majority of consumers even under extreme conditions, less than ideal usage, or in varying weather conditions."<sup>34</sup> An SPF 50 sunscreen provides only about a 1.3 percent increase in absorption of erythema UV radiation, and FDA stated it believed that the nonlinearity of the SPF rating system is confusing to consumers and would be difficult to explain through labeling. Furthermore, it doubted the ability of current testing models to accurately measure high SPF values. Therefore, FDA concluded that all SPF values above 30 should be labeled either "30+" or "30 plus," and any product labeled with a higher SPF value would be considered misbranded, in violation of the FD&C Act.<sup>35</sup> At the same time, FDA stated that it "invites interested persons to continue developing the test methods needed to measure high SPF values, and to submit the data in support of such methods to FDA."<sup>36</sup>

---

<sup>34</sup> Sunscreen Drug Products for Over-The-Counter Use; Final Monograph, 64 Fed. Reg. 27666, 27674 (May 21, 1999).

<sup>35</sup> 64 Fed. Reg. at 27675.

<sup>36</sup> 64 Fed. Reg. at 27675.

Those opposed to the SPF labeling requirement have argued that there is a lack of data suggesting a link between high SPF values and safety problems, there is a benefit of high SPF products for people with very sensitive skin, and there are new formulations that achieve high SPF products with lower active ingredient concentrations.<sup>37</sup> It has also been argued that FDA's policy to prevent a race to the top of SPF levels is paternalistic and greatly interferes with consumer autonomy.<sup>38</sup> While these arguments of the opposition are valid, ultimately the decision to limit the labeling to "30+" was a wise decision. SPF is arguably the defining factor of a sunscreen and "the driving force behind the choice of sunscreen product."<sup>39</sup> While products do not generally explain what SPF even means, the number is a simple way to quantify a sunscreen's worth. An SPF 85 sunscreen does not appear to be only minimally superior to an SPF 30 sunscreen. The high value could easily lead some wearers to be less diligent in reapplying a product that appears more potent than it is. Additionally, as noted by FDA, perception of sunburn protection should not be limited to SPF value. An optimal balance of factors is needed, including irritation potential and UVA radiation protection.<sup>40</sup> Allowing SPF values to soar creates an undue emphasis on that single factor, which is particularly dangerous for consumers given the unintuitive incremental benefits of high SPF values in addition to harmful UVA radiation. The "30+" decision was, therefore, ultimately a beneficial change to sunscreen labeling, considering the level of scientific knowledge available at the time.

An additional beneficial change to labeling was the regulation of waterproof claims. The final monograph requires products that pass the water resistant testing procedures to be labeled either "water resistant" or "water/sweat resistant," and it requires products that satisfy the very

---

<sup>37</sup> 64 Fed. Reg. at 27675.

<sup>38</sup> Perham Gorji, *OTC Sunscreen Drug Products: Toward Greater Protection*, FOOD AND DRUG LAW: AN ELECTRONIC BOOK OF STUDENT PAPERS 1, 12 (1997), [http://www.law.harvard.edu/faculty/hutt/book\\_index.html](http://www.law.harvard.edu/faculty/hutt/book_index.html).

<sup>39</sup> Nash, *supra* note 11, at 63.

<sup>40</sup> 64 Fed. Reg. at 27675.

water resistant testing procedures to be labeled “very water resistant” or “very water/sweat resistant.”<sup>41</sup> This mandated terminology would prevent manufacturers from using common terms, such as “waterproof.” FDA discussed this issue thoroughly in the tentative final monograph and expressed a concern that “waterproof” could be interpreted as describing “something that is completely resistant to water regardless of time of immersion.”<sup>42</sup> Indeed, “waterproof” does invite a strong interpretation of the sunscreen’s power to withstand water. Furthermore, water resistance is not an indication of ability to withstand friction, as up to 85% of sunscreen on the skin can be removed from towel drying off.<sup>43</sup> Thus, these sunscreens should still be reapplied after swimming, vigorous activity, or towel drying.<sup>44</sup> While this word change may be subtle, and to some may even appear hypercritical, labeling word choice should be analyzed extensively in order to best protect the consumer. Advertising depends on subtle word choice, and FDA should not allow potentially deceptive language on the label of an important health product.

Also on the subject of word choice, the final monograph does not allow potentially misleading statements, such as “help[s] prevent skin damage,” since skin damage can occur even with the use of sunscreen and without a visible sunburn.<sup>45</sup> Instead the monograph allows a product to contain this type of claim only if it adheres to the exact phrase, “Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.”<sup>46</sup> Furthermore, FDA banned as nonmonograph phrases such as “shields from,” “protects from,” “filters,” and “screens out”

---

<sup>41</sup> 21 C.F.R. § 352.50.

<sup>42</sup> Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 58 Fed. Reg. 28194, 28228 (1993).

<sup>43</sup> Patricia Poh Agin, *Water Resistance and Extended Wear Sunscreens*, 24 DERMATOLOGIC CLINICS 75, 76 (2006).

<sup>44</sup> *Id.*

<sup>45</sup> 64 Fed. Reg. at 27676-77.

<sup>46</sup> 21 C.F.R. § 352.52(e)(2).

because they suggest a false sense of protection.<sup>47</sup> FDA also decided to ban the term “sunblock” as nonmonograph due to concern that the word may be viewed as an absolute term implying that it blocks all light from the sun.<sup>48</sup> These detailed regulations together work to create an honest and balanced tone on sunscreen labeling. The benefits of sunscreen should surely be praised, but sunscreen products also should not lure customers into a false sense of security.

An additional labeling change set forth in the final monograph is a set of three product categories to accompany SPF values: minimal sunburn protection (for products with SPF 2 to under 12), moderate sunburn protection (for products with SPF 12 to under 30), and high sunburn protection (for products with SPF 30 and higher).<sup>49</sup> These categories were reduced from the earlier proposed five categories and also removed proposed language referencing the prevention of tanning.<sup>50</sup> The ranking of SPF values, while arguably superfluous, further shows an effort to reach the public in a simple and informative way. This simple explanation shows a great improvement from the unregulated use of very large SPF values that could easily mislead consumers. In sum, the labeling regulations in the final monograph represent FDA’s commitment to provide safe and clear information for the public. Nevertheless, in spite of the abundant consumer friendly provisions, in 2001 FDA issued a stay of the majority of the final monograph.<sup>51</sup>

---

<sup>47</sup> 64 Fed. Reg. at 27677.

<sup>48</sup> 64 Fed. Reg. at 27680.

<sup>49</sup> 64 Fed. Reg. at 27679.

<sup>50</sup> 64 Fed. Reg. at 27679.

<sup>51</sup> Sunscreen Drug Products for Over-the-Counter Human Use; Partial Stay, 66 Fed. Reg. 67485 (2001).

## The 2007 Proposed Rules

The 2007 proposed rules most notably reflect FDA's prior stated concern about the lack of an adequate UVA test. From among the more than ten different UVA tests,<sup>52</sup> FDA has chosen two required tests to determine a sunscreen's UVA rating. It proposes both an in vitro and in vivo test to be performed on each product, with a rating adopting the lower of the two test results.<sup>53</sup> The rating will consist of both stars and a category descriptor, with the categories "low," "medium," "high," and "highest" each corresponding respectively to one, two, three, or four stars.<sup>54</sup> Thus, if a sunscreen scored a medium on the in vitro test and a high on the in vivo test, the product would display a UVA score of medium with a picture of two stars. This rating will be displayed in an equally prominent manner as the UVB/SPF rating, in spite of comments claiming that UVB radiation is still more of a concern than UVA radiation.<sup>55</sup> Additionally, a product with no adequate UVA protection will be required to have labeling that states, "no UVA protection."<sup>56</sup>

Some people still maintain that SPF should be the most prominent indicator on sunscreen labels based on the claim that most UV-induced skin damage is a result of short wavelength UVB radiation.<sup>57</sup> These advocates support a simple broad spectrum designation for products with UVA protection, so as to not detract from the SPF value.<sup>58</sup> By rejecting these UVB-centric proposals, the FDA has affirmed its assessment of the importance of UVA protection and the need for sunscreen products to more adequately address the full spectrum of radiation and sun

---

<sup>52</sup> FDA Press Conference on Issues Related to Sunscreens, at 4 (Aug. 23, 2007).

<sup>53</sup> Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amended Final Monograph, 72 Fed. Reg. 49070, 49104 (Aug. 27, 2007).

<sup>54</sup> 72 Fed. Reg. at 49083.

<sup>55</sup> 72 Fed. Reg. at 49083.

<sup>56</sup> 72 Fed. Reg. at 49112.

<sup>57</sup> Nash, *supra* note 11, at 70.

<sup>58</sup> *Id.* at 71.

induced skin dangers. This conclusion is supported by much evidence and worldwide consensus, as studies have shown that exposure to long wavelength UVA radiation damages the skin and can lead to cancer.<sup>59</sup>

Not only does evidence exist showing the need for UVA protection independent of other factors, but some studies support the “compensation hypothesis,” which holds that UVB protection may actually increase the harmful effects of UVA radiation, such as melanoma. The theory suggests that people can be exposed to UVA radiation longer, based on the UVB protection’s effectiveness in preventing the skin from burning. Without UVB protection, a person would not stay in the sun as long and, thus, would be better protected from UVA radiation.<sup>60</sup> Evidence exists to both support and refute this hypothesis,<sup>61</sup> but at the very least, the hypothesis supports the broader principle that UVB protection does not address the dangers of UVA radiation. The lack of sunburn resulting from exposure to UVA radiation further stresses the need to raise UVA awareness and protect skin from effects that are not immediately apparent.

The 2007 proposed rules also amend the SPF labeling on sunscreen products. Rather than limiting SPF values to “30+,” the agency is now allowing values up to “50+.”<sup>62</sup> This change is related to new testing data showing that the SPF test produces accurate results for products between SPF 30 and 50, which was not available at the time of the final monograph.<sup>63</sup> However, the “30+” labeling restriction of the final monograph was met with some strong complaints, which may be applicable to the new “50+” limit as well. Some comments asserted these limits, in addition to some other labeling restrictions, violated the right to freedom of

---

<sup>59</sup> *Id.* at 65.

<sup>60</sup> Eide, *supra* note 2, at 120.

<sup>61</sup> *Id.* at 121.

<sup>62</sup> 72 Fed. Reg. at 49072.

<sup>63</sup> 72 Fed. Reg. at 49079.

speech guaranteed by the First Amendment of the Constitution.<sup>64</sup> These comments allege that FDA has failed to meet its burden to prove that the claims are misleading or that the restrictions on the speech directly advance a substantial government purpose.<sup>65</sup> FDA maintains, however, that the labeling requirements are “reasonably related to the Government’s interest in promoting the health, safety, and welfare of consumers and because they are not an ‘unjustified or unduly burdensome’ disclosure requirement.”<sup>66</sup>

FDA presents a strong argument in support of the labeling restrictions. The comments do not appear to appreciate the overall purpose of the monograph process as compared to the NDA process. As discussed earlier, the monograph system is meant to approve drugs that are generally recognized as safe and effective. The labeling requirements prescribed in the monograph directly relate to consumer understanding and the safe and effective use of the product.<sup>67</sup> Since SPF in particular is such a strong identifying component of sunscreen products,<sup>68</sup> a labeling restriction based on scientific data that high SPF values do not supply a worthwhile benefit is quite reasonable. SPF values in the United States reached the extremely high level of “100+” in 2009, further highlighting the need to stop the fruitless race to the top.<sup>69</sup> Perhaps the newly allowed “50+” label will satisfy some of the critics of the “30+” limit. Since SPF values have remained unregulated in spite of the final monograph, high SPF values are quite common on store shelves, and so customers used to relying on high SPF values may be more accepting of a higher cap.

---

<sup>64</sup> 72 Fed. Reg. at 49077.

<sup>65</sup> 72 Fed. Reg. at 49077.

<sup>66</sup> 72 Fed. Reg. at 49077.

<sup>67</sup> See 72 Fed. Reg. at 49077.

<sup>68</sup> See 72 Fed. Reg. at 49804.

<sup>69</sup> Osterwalder, *supra* note 5, at 477.



Also relating to UVB labeling, the term “UVB” will now be included before the term “SPF,” so that consumers will understand that SPF is only an indicator of UVB protection.<sup>70</sup> The SPF values will also have a corresponding category descriptor that adopts the same terms that are used to describe UVA values (low, medium, high, and highest). This change amends the three categories adopted in the 1999 final monograph (minimal, moderate, and high).<sup>71</sup> These new requirements are practical responses to the new UVA labeling, as using the same rating system for both factors will likely present the information in the clearest way possible.

In addition, FDA has refined the already carefully analyzed word choice required in the final monograph. The optional “sun alert” statement in the final monograph has been changed to a mandatory revised “sun alert” in the “Warnings” section of the label.<sup>72</sup> The mandatory alert states, “UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.”<sup>73</sup> Additionally, the proposed regulations now will only allow manufactures the choice of either “liberally” or “generously” in the directions section of the label. The previously allowed term, “smoothly,” will be eliminated due to vagueness.<sup>74</sup> Furthermore, the directions will include reapplying instructions, rather than just applying instructions.<sup>75</sup>

These instructions attempt to address the particular challenge of encouraging proper use. Consumers typically apply less sunscreen than is needed to establish the SPF that manufacturers claim, so the actual SPF obtained may only be 20% to 50% of the advertised SPF.<sup>76</sup> One study

---

<sup>70</sup> 72 Fed. Reg. at 49077.

<sup>71</sup> 72 Fed. Reg. at 49077.

<sup>72</sup> 72 Fed. Reg. at 49072.

<sup>73</sup> 72 Fed. Reg. at 49072.

<sup>74</sup> 72 Fed. Reg. at 49072.

<sup>75</sup> 72 Fed. Reg. at 49072.

<sup>76</sup> Eide, *supra* note 2, at 120.

conducted in Australia found that the median amount of sunscreen applied was 0.8 mg.cm,<sup>2</sup> which is less than half the amount that was needed to achieve the SPF on the label.<sup>77</sup> Furthermore, many people do not adequately appreciate the need to reapply sunscreen, particularly when it is labeled “waterproof.”<sup>78</sup> This is especially important, given another study that found that reapplication of sunscreen produced a benefit two to three times as great as that of a single application.<sup>79</sup> Directions and warnings that emphasize these issues could help to educate the public and help people maximize the benefits of sunscreen.

The 2007 proposed rules also address concerns regarding the best way to label cosmetics containing sunscreen. The prevalent use of face makeup advertising SPF levels on product labels also has created new challenges to encouraging proper and effective use of these products. Cosmetic products containing sunscreen became increasingly popular by the end of the 20<sup>th</sup> century.<sup>80</sup> Sun protection in foundation is an excellent idea that encourages daily use of sun protection, but it also creates an opportunity for inaccurate assumptions based on misleading labeling. For example, foundation tends to migrate on the face, as a study showed that makeup tends to collect in facial lines soon after application.<sup>81</sup> An additional study showed that foundation migrated within 2 hours or less on women with oily skin and within 4 hours for all of the women.<sup>82</sup> Thus, it seems that foundation products may not be as effective as a sunscreen with a comparable SPF. But since SPF is the defining feature of sun protection, most foundation wearers likely do not know that their product may not adequately maintain the protection advertised on the label.

---

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> Sarah E. Schaffer, *Reading our Lips: The History of Lipstick Regulation in Western Seats of Power*, 62 FOOD & DRUG L.J. 165, 215 (2007).

<sup>81</sup> Agin, *supra* note 42, at 77.

<sup>82</sup> *Id.*

A major concern with makeup products containing sunscreen is improper use and a lack of understanding of the limits of its protection. Foundation is likely not often applied “generously,” as sunscreen should be.<sup>83</sup> Some comments to the final monograph note that many consumers use face and hand cosmetics containing sunscreen as their primary and sometimes only source of sun protection.<sup>84</sup> Thus, labeling on these cosmetics is very likely just as important as the labeling on traditional sunscreens. Others, however, were concerned with accommodating the new labeling requirements on small packaging, particularly for products used on only a small part of the face, such as lip balm and lipstick.<sup>85</sup> In the proposed rule, FDA struck a balance in deciding how to handle these issues. Specifically it allowed labeling modifications for sunscreen products that are labeled for use only on particular small areas of the face and that are sold in small packages.<sup>86</sup> This would not include facial foundation, moisturizer, or other products used on larger areas of the face.<sup>87</sup>

Requiring the sunscreen warnings and labeling on facial cosmetics is an essential step to take toward greater sun protection. Furthermore, the exemptions for small products only used on small areas of the face are sensible, particularly in light of the risk that manufacturers would choose to remove all sun protection from small products rather than accommodate burdensome labeling requirements.<sup>88</sup> The UVA labeling specifically will help consumers, as labels declaring “no UVA protection” will hopefully educate consumers about the fact that SPF is not a comprehensive indicator of sun protection. However, facial cosmetics may be in need of further warnings due to foundation’s migration tendencies on the face,<sup>89</sup> and also due to different

---

<sup>83</sup> See 72 Fed. Reg. at 49072.

<sup>84</sup> 72 Fed. Reg. at 49076.

<sup>85</sup> 72 Fed. Reg. at 49076.

<sup>86</sup> 72 Fed. Reg. at 49077.

<sup>87</sup> 72 Fed. Reg. at 49077.

<sup>88</sup> 72 Fed. Reg. at 49077.

<sup>89</sup> See Agin, *supra* note 42, at 77.

application practices of foundation as opposed to sunscreen. Makeup wearers should know that applying small amounts of the product lowers the SPF and increases risk of sun damage. While over-labeling could risk turning customers away from reading any of the label, additional warnings should at least be considered and further efforts to understand the relative protection of foundation as compared to traditional sunscreen should be made.

In sum, these new regulations build on the final monograph's efforts to improve sunscreen labeling to best protect consumers. The inclusion of UVA ratings and detailed changes to allowable and mandated language provide a better tool for consumers to make an educated choice of sunscreen. Nonetheless, as time passes without any regulations becoming finalized, consumers are unable to receive the benefits of FDA's conclusions and may be harming their health due to misunderstanding of sunscreen labels and the risks of prolonged sun exposure.

## **Effects of FDA's Failure to Finalize Regulations**

In 1978, when FDA issued an advance notice of proposed rulemaking for sunscreen products, it is hard to imagine the agency would have predicted that final regulations would still not exist in 2011. The establishment of norms and standards is crucial to UV protection.<sup>90</sup> FDA's failure to implement final regulations for so long has led to products being sold that do not need to conform to the thoroughly researched and analyzed labeling standards that FDA has already created and continues to create. For example, there is currently more or less worldwide consensus that SPF labeling should be capped at "50+," but the United States has yet to

---

<sup>90</sup> Osterwalder, *supra* note 5, at 477.

affirmatively commit to this standard.<sup>91</sup> In spite of continually changing science, FDA has had many opportunities to codify regulations based on the best available science, which would have improved sunscreen labeling greatly. Even in 2011, sunscreen labeling would likely be more helpful to the consumer if it adhered to the 1999 final monograph rather than the whims of manufacturers and advertising executives.

This is not to say that any type of stay was inappropriate after the 1999 final monograph. The lack of an accepted standard to test UVA protection certainly created a gaping hole in the monograph. For example, the monograph tied the issue of ingredient concentration levels to product performance, which was in turn evaluated based on the SPF level.<sup>92</sup> This decision was due to FDA's decision to remove minimum concentration requirements for sunscreen active ingredients.<sup>93</sup> The new scheme would link the concentration directly to SPF, so that the concentration of each active ingredient must be sufficient to contribute to a minimum of SPF of two and the final SPF must be no less than the number of active ingredients multiplied by two.<sup>94</sup> This amended requirement would ensure that each ingredient is actually useful to the effectiveness of the finished product, while also protecting against the needless inclusion of active ingredients to meet a minimum requirement. Furthermore, this new requirement is more compatible with manufacturers' creations of innovative formulation, which could also lower the risk of adverse reactions.<sup>95</sup>

At the same time, a product performance evaluation based solely on SPF is incomplete, as it ignores the important UVA component. Before the final monograph was released, it was

---

<sup>91</sup> *Id.*

<sup>92</sup> Sunscreen Drug Products for Over-The-Counter Use; Final Monograph, 64 Fed. Reg. 27666, 27672 (May 21, 1999).

<sup>93</sup> 64 Fed. Reg. at 27672.

<sup>94</sup> 64 Fed. Reg. at 27672.

<sup>95</sup> See Gorji, *supra* note 37, at 15.

suggested in a scholarly article that ingredient concentration levels should be based on total product performance, which would include a test for UVA protection.<sup>96</sup> This would very likely improve the FDA's ability to maximize ingredient effectiveness by pinpointing with increased accuracy the desirable concentration levels of ingredients. Thus, this specific issue would have benefited from extra time to sort through scientific data concerning UVA testing methods.

Nonetheless, the stay was overinclusive. It set aside labeling regulations that did not depend on new UVA radiation measurement data. One could argue that it would cause more confusion to only stay part of the monograph rather than put the entire regulation on hold, but in fact, the FDA did only issue a partial stay.<sup>97</sup> Parts 310, 700, and 740 of the regulation were excluded from the stay.<sup>98</sup> These sections relate to FDA's general administrative authority (part 310) and the labeling and packaging of cosmetics (parts 700 and 740).<sup>99</sup> Thus, the agency showed its willingness to leave some regulations in tact, but still issued a sweeping stay of part 352 of the regulation.

Consequently, many of the labeling issues that currently exist could have been addressed before the UVA assessment technology was settled. In fact, many of these issues were addressed, thoroughly analyzed, amended, and finalized, only to be stayed and rendered unfinal. For example, the word choice restrictions on water resistant claims could have been finalized without waiting for UVA testing to be further developed. Even if FDA unwaveringly wanted to change the water resistant testing procedures to incorporate UVA protection, the actual word choice on the sunscreen label is independent of the testing mechanism. In other words, whether

---

<sup>96</sup> *Id.*

<sup>97</sup> Sunscreen Drug Products for Over-the-Counter Human Use; Partial Stay, 66 Fed. Reg. 67485, 67485 (2001).

<sup>98</sup> 66 Fed. Reg. at 67485.

<sup>99</sup> 64 Fed. Reg. at 27693.

protection from water is described as “waterproof” or “water resistant” is unrelated to the actual test used.

Similarly, the SPF cap of “30+” mandated in the final monograph is unrelated to UVA testing procedures. While it is true that more data has been collected and examined since 1999, which has led FDA to raise the cap to “50+,”<sup>100</sup> the “30+” limit represented the best evidence at the time and would have helped to protect consumers from the false sense of security of an SPF 85 sunscreen. Additionally, the prohibition of the term “sunblock” could have been put into effect. This word choice was not dependent on scientific testing procedures. And even on the topic of UVA radiation, sunscreen products without any UVA protection could have been labeled as such. This would have at least brought the UVA issue to the attention of consumers and could have helped people understand that SPF alone is not an indication of complete sun protection. Indeed much of the subtle labeling does not concern UVA testing, and so the public has needlessly been deprived of clearer and less misleading labeling.

While it is understandable that FDA wants to issue regulations that contain the best science and technology possible, this goal loses its benefits when finality and clarity are continually pushed further into the future. Science is constantly progressing, and waiting for the absolute best testing methods to emerge is futile. FDA has chosen to wait until 2007 to propose rules regulating the testing and labeling of UVA protection—and even longer to pass final binding regulations. But even then, the science will not be complete. Particularly in regards to UVA protection, many tests exist that can continue to be improved and modified to achieve more exact results. A recent study rated the status of sunscreen assessment and measurement at about

---

<sup>100</sup> Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amended Final Monograph, 72 Fed. Reg. 49070, 49079 (Aug. 27, 2007).

50% on the poor-to-perfect scale.<sup>101</sup> While many methods exist to assess sunscreens, the researchers concluded that more reliable and realistic methods were still far off from present capabilities.<sup>102</sup> The gains of scientific discovery are lost if the principles discovered are never put into action. Even if the science of 1999 is imperfect, the failure to codify regulations based on those discoveries has left the public with far less protection.

One direct effect of the sunscreen's rulemaking process is that much confusion exists as to the current regulation of sunscreen. The prolonged and unfinalized rulemaking, in addition to evasive statements by FDA, has led to confusion about the current standards governing sunscreen products on shelves today. News articles available to the public make a wide range of assertions about the legal standards currently governing sunscreen labels, ranging from the 1978 notice of rulemaking to the 1999 final monograph.<sup>103</sup> At an FDA press conference in 2007, the agency's representatives struggled to explain the legal grey area that exists. After two attempts at answering questions from the press regarding the status of the 1999 monograph, a third media correspondent stated, "I'm completely baffled by this 1999 Rule. Was – did it never go into a test and why are manufacturers allowed to ignore it?"<sup>104</sup>

In fact, in the press conference about the proposed 2007 regulations, five questions were asked attempting to clarify the status of the 1999 rules. An FDA representative attempted to clarify the issue by explaining why sunscreen SPF values above 30 are widely present in stores, stating that "[...] we have enforcement discretion where we have a rule out and we have – it hasn't gone into effect yet."<sup>105</sup> It is not surprising that others in attendance remained confused,

---

<sup>101</sup> Osterwalder, *supra* note 5, at 477.

<sup>102</sup> *Id.*

<sup>103</sup> See, e.g., Kim McCabe & Greg Hunter, *Lawsuit Asks: Is Your Sunscreen Doing Its Job?*, CNN, June 13, 2006, [http://articles.cnn.com/2006-06-13/health/hunter.sunscreen\\_1\\_uv-b-protection-sunscreen-manufacturers-sunscreen-makers?\\_s=PM:HEALTH](http://articles.cnn.com/2006-06-13/health/hunter.sunscreen_1_uv-b-protection-sunscreen-manufacturers-sunscreen-makers?_s=PM:HEALTH) (stating that sunscreen manufacturers follow FDA rules released in 1993).

<sup>104</sup> FDA Press Conference on Issues Related to Sunscreens, at 25 (Aug. 23, 2007).

<sup>105</sup> *Id.* at 13.



since “enforcement discretion” is an odd phrase to describe a rule that is not yet in effect. Can manufacturers be legally bound to a regulation not yet in effect? Later, an FDA representative stated, “after we find that [a sunscreen manufacturer’s] labeling deviates significantly from a proposed regulation such that it makes the product no longer safe and effective, we would take enforcement action against them.”<sup>106</sup> The speaker added, “we do have to prioritize our enforcement resources and we are most concerned about things that egregiously have safety concerns.”<sup>107</sup> This last statement is particularly peculiar, as FDA seems to defend the nonenforcement of the 1999 rules by pointing to the lack of resources rather than the lack of actually binding rules. By emphasizing the agency’s enforcement discretion, the FDA representatives seemed anxious to avoid admitting that the 1999 rule was not in effect and that the many labeling conclusions made in the rule are free to be ignored, aside from serious safety concerns.

At the same time, the FDA representatives did admit that “manufacturers are not required to comply with [the 1999 final rule].”<sup>108</sup> But they also added that manufacturers can voluntarily comply with the proposed regulations and oftentimes do voluntarily comply.<sup>109</sup> The explanation of the 1999 rule was delivered little by little in response to the five questions about the rule. Thus the FDA representatives begrudgingly described the nonbinding reality of the 1999 rule, while emphasizing discretion in special circumstances of safety concern to enforce the rule. Even after the five explanations of the 1999 rule, the FDA closed the press conference with ambiguity. In response to a question asking what the ingredients of most sunscreens are today, the FDA representative responded, “There are 16 active ingredients in the 1999 Final Rule and

---

<sup>106</sup> *Id.* at 31.

<sup>107</sup> *Id.* at 32.

<sup>108</sup> *Id.* at 12.

<sup>109</sup> *Id.* at 22.

those are the same 16 active ingredients in this proposed rule today.”<sup>110</sup> This answer, of course, does not answer the question, but further highlights the evasive explanations of current sunscreen regulations.

The lack of awareness of the public is likely due in part to the lack of implementation of final regulations. The advertising of sunscreen products, in addition to campaigns led by health organizations and sunscreen issues discussed by the media, are the major influencing forces on public awareness.<sup>111</sup> FDA has stated that the reasons for the stay of the 1999 final monograph are distinct from whether the agency believes the information in the rule is accurate and reflective of current plans.<sup>112</sup> This admission highlights the problem. By hoarding both conclusions and labeling improvement plans, FDA is effectively keeping information away from the public. While most people have likely seen the label of a sunscreen bottle, they likely have not seen the text of the 1999 final monograph.

As the public and industry continue to wait for final regulations, many issues continue to plague sunscreen labeling. The current state of sunscreen bottles is far from in line with the standards set forth in the final monograph, in spite of FDA’s insistence that many manufacturers voluntarily have chosen to abide by the stayed regulations.<sup>113</sup> Without legally binding rules, it is hard to appreciate the incentive for lowering labeled SPF values and modifying claims to make the imperfections of sunscreen more readily apparent to customers. In 2006 it was reported that more than 80% of marketed sunscreen products in the United States claimed some type of UVA protection, while only 56% contained a recognized UVA-1 filter.<sup>114</sup> Furthermore, terms such as “waterproof,” “sunblock,” and “SPF 85+” are free to appear on labels in spite of the fact that

---

<sup>110</sup> *Id.* at 36.

<sup>111</sup> Osterwalder, *supra* note 5, at 479.

<sup>112</sup> FDA Press Conference on Issues Related to Sunscreens, at 32 (Aug. 23, 2007).

<sup>113</sup> *Id.* at 31.

<sup>114</sup> Nash, *supra* note 11, at 71.

FDA has acknowledged the misleading quality of such terms at least since 1999.<sup>115</sup> Such variability among standards hinders consumer protection and informed choice.

Throughout all this time, lawmakers and the public have been getting impatient. The SUN Act was introduced by Senator Dodd on May 20, 2009, but it was referred to the Committee on Health, Education, Labor, and Pensions with no further action taken.<sup>116</sup> This bill sought to force FDA action by legally enacting the 2007 proposed rules within 180 days of enactment of the SUN Act, unless FDA issued a final rule before that time.<sup>117</sup> In spite of general frustration, FDA has not finalized regulations.

Perhaps what is most concerning, however, is the continued uncertainty of the future. In response to the proposed rule released in 2007, the FDA has received over 3000 comments from the public.<sup>118</sup> Analyzing and responding to the comments' concerns and suggestion is no easy task and should not be taken lightly. However, this careful analysis has extended the timeline already and will likely continue to do so. As of 2009, the International Organization for Standardization had been drafting standards for both SPF and UVA testing procedures. Also in 2009, Matthew Holman, the deputy director of the Division of Nonprescription Regulation Development, stated that FDA would not wait for international standards to be set and harmonized among countries before finalizing sunscreen regulations.<sup>119</sup> Instead, FDA would amend finalized regulations in the future, in light of finalized international standards.<sup>120</sup> This intention certainly seems to be the most prudent course of action, but FDA's assertion to set

---

<sup>115</sup> See Sunscreen Drug Products for Over-The-Counter Use; Final Monograph, 64 Fed. Reg. 27666 (May 21, 1999).

<sup>116</sup> Bill Summary & Status S.1112, Library of Congress, <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:SN01112:@@@L&summ2=m&> (last visited May 3, 2011).

<sup>117</sup> SUN Act, S. 1112, 111th Cong. (2009).

<sup>118</sup> *FDA to Issue Final Sunscreen Rule After International Meeting*, 15 FDA WEEK 35 (2009).

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

standards in light of uncertainty in the scientific community also seems at odds with the historical record of sunscreen regulation for the past few decades.

## **Conclusion**

While FDA has made impressive changes to sunscreen labeling requirements in order to improve the knowledge and sun protection of the public, these changes are purely optional. In reality, customers are faced with a wide variety of sunscreen products making a wide variety of claims and have little protection from FDA. A great deal of time and effort has been put into sunscreen regulation, and it is a shame that this regulation has not been implemented. A product as vital to health as sunscreen should be stringently regulated to better educate the public, and the label of the product is one of the most effective ways of reaching people. The future of sunscreen regulation remains uncertain, and as the country continues to wait, the SPF 85+ waterproof sunblocks continue to fly off the drugstore shelves.